4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2012-N-0473]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Irradiation in the Production, Processing, and Handling of Food

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202-395-7285, or emailed to oira_submission@omb.eop.gov. All comments should be identified with the OMB control number 0910-0186. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT:

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SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Irradiation in the Production, Processing, and Handling of Food--21 CFR Part 179 (OMB Control Number 0910-0186)--Extension

Under sections 201(s) and 409 of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 321(s) and 348), food irradiation is subject to regulation under the food additive premarket approval provisions of the FD&C Act. The regulations providing for uses of irradiation in the production, processing, and handling of food are found in part 179 (21 CFR part 179). To ensure safe use of a radiation source, § 179.21(b)(1) requires that the label of sources bear appropriate and accurate information identifying the source of radiation and the maximum (or minimum and maximum) energy of radiation emitted by X-ray tube sources. Section 179.21(b)(2) requires that the label or accompanying labeling bear adequate directions for installation and use and a statement supplied by FDA that indicates maximum dose of radiation allowed. Section 179.26(c) requires that the label or accompanying labeling bear a logo and a radiation disclosure statement. Section 179.25(e) requires that food processors who treat food with radiation make and retain, for 1 year past the expected shelf life of the products up to a maximum of 3 years, specified records relating to the irradiation process (e.g., the food treated, lot identification, scheduled process, etc.). The records required by § 179.25(e) are used

by FDA inspectors to assess compliance with the regulation that establishes limits within which radiation may be safely used to treat food. The Agency cannot ensure safe use without a method to assess compliance with the dose limits, and there are no practicable methods for analyzing most foods to determine whether they have been treated with ionizing radiation and are within the limitations set forth in part 179. Records inspection is the only way to determine whether firms are complying with the regulations for treatment of foods with ionizing radiation.

In the Federal Register of May 17, 2012 (77 FR 29352), FDA published a 60-day notice requesting public comment on the proposed collection of information. One comment was received outside the scope of the four collection of information topics solicited by the notice.

Description of respondents: Respondents are businesses engaged in the irradiation of food.

FDA estimates the burden of this collection of information as follows:

Table 1.--Estimated Annual Recordkeeping Burden[1]

21 CFR Section	No. of Recordkeepers	No. of Records per Recordkeeper	Total Annual Records	Average Burden per Recordkeeping	Total Hours
179.25(e), Large Processors	3	300	900	1	900
179.25(e), Small Processors	4	30	120	1	120
Total					1,020

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

FDA bases its estimate of burden for the recordkeeping provisions of § 179.25(e) on the Agency's experience regulating the safe use of radiation as a direct food additive. The number of firms who process food using irradiation is extremely limited. FDA estimates that there are 3 irradiation plants whose business is devoted primarily (i.e., approximately 100 percent) to

irradiation of food and other agricultural products. Four other firms also irradiate small quantities of food. FDA estimates that this irradiation accounts for no more than 10 percent of the business for each of these firms. Therefore, the average estimated burden is based on 3 facilities devoting 100 percent of their business to food irradiation (3 x 300 hours = 900 hours for recordkeeping annually), and 4 facilities devoting 10 percent of their business to food irradiation (4 x 30 hours = 120 hours for recordkeeping annually).

No burden has been estimated for the labeling requirements in §§ 179.21(b)(1), 179.21(b)(2), and 179.26(c) because the information to be disclosed is information that has been supplied by FDA. Under 5 CFR 1320.3(c)(2), the public disclosure of information originally supplied by the Federal Government to the recipient for the purpose of disclosure to the public is not a collection of information.

Dated: July 18, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

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